5. 510(k) Summary

JAN 26 2007

vidacare

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SUMMARY

Submitter's name: Vidacare Corporation
Address: 722 Isom Road
San Antonio, TX 78216

Phone: 210-375-8500
Fax number: 210-375-8537

Name of contact person: Grace Holland
Regulatory Specialists, Inc
3722 Ave. Sausalito
Irvine, CA 92606
Phone: 949-262-0411
Fax: 949-552-2821

Date the summary was prepared: November 3, 2006

Name of the device: EZ-MIO Sternal
Trade or proprietary name: EZ-MIO Sternal
Common or usual name: Intraosseous Infusion System
Classification name: Hypodermic single lumen needle

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K052195	1	EZ-MIO Manual Driver	1	Vidacare Corp.
2	K970380	2	F.A.S.T. 1 Intraosseous Infusion System (powered)	2	PYNG Medical Corp.

Description of the device:

The EZ-MIO Sternal is very similar to the EZ-MIO, manual driver, previously cleared under 510(k) K052195. The two minor differences between the devices are in the driver and addition of a collar to the needle set. The predicate EZ-MIO consists of a proprietary pentagon shaft permanently attached to an ergonomically designed reusable driver. The EZ-MIO Sternal is single use and has a smaller driver permanently attached to the needle set. The second difference is the EZ-MIO Sternal has a permanently attached collar added to the same needle set used by the EZ-MIO. The collar is used to control depth of penetration. Both products utilize the same needle set and are designed to allow the user to manually insert a needle set consisting of a stylet and catheter through the cortex of a bone to a desired depth within the bone marrow to facilitate the infusion of desired fluids. After insertion of the needle set, both systems function identically by allowing the user to remove a stylet from the catheter by turning the stylet hub counter clockwise leaving a standard Luer lock catheter securely seated in the bone. The catheter Luer lock permits attachment of standard syringes and IV tubing for administration of drugs and fluids (not supplied). The needle set size used in the sternum is the identical needle set used by the predicate EZ-MIO (15G X 25mm). The EZ-MIO system is approved for use in the proximal tibia under 510(k) K052195. This submission requests an indication for use of the EZ-MIO Sternal in the sternum location already established by the predicate device Pyng F.A.S.T.1 (K970380).

Indications:

Sternal IO access is indicated for adult patients when rapid fluid or pharmacological resuscitation is required in emergencies

Summary of the technological characteristics of our device compared to the predicate devices:

The EZ-MIO Sternal has the exact same technology as the EZ-MIO cleared under 510(k) K052195. There have been no major changes to the design or components and therefore the comparison of technological characteristics such as target

population, needle design, technique, sterility, biocompatibility and where it is used is identical.

Vidacare also wishes to use as a predicate F.A.S.T. 1 Intraosseous Infusion System, K970380, by PYNG Medical Corp., as this system has been cleared for use in the sternal location for which we are applying.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vidacare Corporation
C/O Ms. Grace Holland
Regulatory Specialist
Regulatory Specialist, Incorporated
3722 Avenue Sausalito
Irvine, California 92606

JAN 26 2007

Re: K063567
Trade/Device Name: EZ-MIO Sternal
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: November 24, 2006
Received: November 28, 2006

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

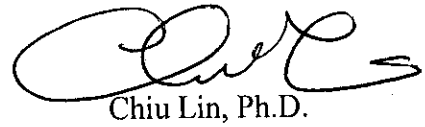
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: EZ-MIO Sternal

Sternal IO access is indicated for adult patients when rapid fluid or pharmacological resuscitation is required in emergencies

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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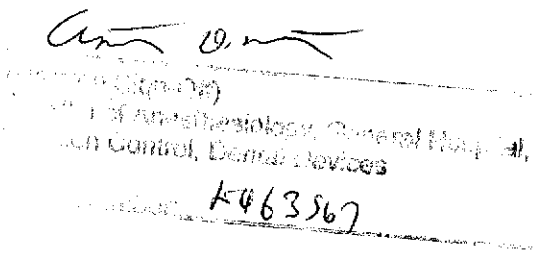
Concurrence of CDRH, Office of Device Evaluation (ODE)



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